General

Guideline Title

Surgical management of stones: American Urological Association/Endourological Society Guideline.

Bibliographic Source(s)

Assimos D, Krambeck A, Miller NL, Monga M, Murad MH, Nelson CP, Pace KT, Pais VM Jr, Pearle MS, Preminger GM, Razvi H, Shah O, Matlaga BR. Surgical management of stones: American Urological Association/Endourological Society guideline. Linthicum (MD): American Urological Association Education and Research, Inc.; 2016 Apr. 50 p. [235 references]

Guideline Status

This is the current release of the guideline.

This guideline updates previous versions: EAU/AUA Nephrolithiasis Guideline Panel. Guideline for the management of ureteral calculi. Baltimore (MD): American Urological Association Education and Research, Inc., European Association of Urology; 2007. 61 p. [92 references]

American Urological Association Education and Research, Inc. Report on the management of staghorn calculi. Linthicum (MD): American Urological Association Education and Research, Inc.; 2005. Various p. [81 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Definitions for the body of evidence strength (Grade A, B, or C), the strength of the recommendations (Strong, Moderate, Conditional), and for statements labeled as Clinical Principle and Expert Opinion are provided at the end of the "Major Recommendations" field.

Note: The surgical management of patients with various stones has been indexed into 13 respective patient profiles. Index Patients 1-10 are non-morbidly obese; non-pregnant adults (≥18 years of age) with stones not thought to be composed of uric acid or cystine; normal renal, coagulation and platelet function; normally positioned kidneys; intact lower urinary tracts without ectopic ureters; no evidence of sepsis; and no anatomic or functional obstruction distal to the stone(s). Index Patients 13 and 14 are children (<18 years of age) with similar characteristics to Index Patients 1-10. Index Patient 15 is a pregnant female with symptomatic renal or ureteral stone(s) with normal renal function without urinary

tract infection (UTI). Detailed descriptions of these patients can be found in the original guideline document under "Index Patients."

Imaging, Pre-operative Testing

Clinicians should obtain a non-contrast computed tomography (CT) scan on patients prior to performing percutaneous nephrolithotomy (PCNL). (*Strong Recommendation; Evidence Level Grade C*)
Clinicians may obtain a non-contrast CT scan to help select the best candidate for shock-wave lithotripsy (SWL) versus ureteroscopy (URS). (*Conditional Recommendation; Evidence Level Grade C*)
Clinicians may obtain a functional imaging study (diethylenetriamine-pentacetic acid [DTPA] or (mercaptoacetyltriglycine [MAGâ€3]) if clinically significant loss of renal function in the involved kidney or kidneys is suspected. (*Conditional Recommendation; Evidence Level Grade C*)
Clinicians are required to obtain a urinalysis prior to intervention. In patients with clinical or laboratory signs of infection, urine culture should be obtained. (*Strong Recommendation; Evidence Level Grade B*)
Clinicians should obtain a complete blood count (CBC) and platelet count on patients undergoing procedures where there is a significant risk of hemorrhage or for patients with symptoms suggesting anemia, thrombocytopenia, or infection; serum electrolytes and creatinine should be obtained if there is suspicion of reduced renal function. (*Expert Opinion*)
In patients with complex stones or anatomy, clinicians may obtain additional contrast imaging if further definition of the collecting system and the ureteral anatomy is needed. (*Conditional Recommendation; Evidence Level Grade C*)

Treatment of Adult Patients with Ureteral Stones

Patients with uncomplicated ureteral stones ≤10 mm should be offered observation, and those with distal stones of similar size should be offered medical expulsive therapy (MET) with α-blockers. (Index Patient 3) (*Strong Recommendation; Evidence Level Grade B*)
Clinicians should offer reimaging to patients prior to surgery if passage of stones is suspected or if stone movement will change management. Reimaging should focus on the region of interest and limit radiation exposure to uninvolved regions. (*Clinical Principle*)
In most patients, if observation with or without MET is not successful after four to six weeks and/or the patient/clinician decide to intervene sooner based on a shared decision making approach, clinicians should offer definitive stone treatment. (Index Patients 1-3) (*Moderate Recommendation; Evidence Level Grade C*)
Clinicians should inform patients that SWL is the procedure with the least morbidity and lowest complication rate, but URS has a greater stone-free rate in a single procedure. (Index Patients 1-6) (*Strong Recommendation; Evidence Level Grade B*)
In patients with mid or distal ureteral stones who require intervention (who were not candidates for or who failed MET), clinicians should recommend URS as first-line therapy. For patients who decline URS, clinicians should offer SWL. (Index Patients 2,3,5,6) (*Strong Recommendation; Evidence Level Grade B*)
URS is recommended for patients with suspected cystine or uric acid ureteral stones who fail MET or desire intervention. (*Expert Opinion*)
Routine stenting should not be performed in patients undergoing SWL. (Index Patients 1-6) (*Strong Recommendation; Evidence Level Grade B*)
Following URS, clinicians may omit ureteral stenting in patients meeting all of the following criteria: those without suspected ureteric injury during URS, those without evidence of ureteral stricture or other anatomical impediments to stone fragment clearance, those with a normal contralateral kidney, those without renal functional impairment, and those in whom a secondary URS procedure is not planned. (Index Patients 1-6) (*Strong Recommendation; Evidence Level Grade A*)
Placement of a ureteral stent prior to URS should not be performed routinely. (Index Patient 1-6) (*Strong Recommendation; Evidence Level Grade B*)
Clinicians may offer α-blockers and antimuscarinic therapy to reduce stent discomfort. (Index patients 1-6) (*Moderate Recommendation; Evidence Level Grade B*)
In patients who fail or are unlikely to have successful results with SWL and/or URS, clinicians may

offer PCNL, laparoscopic, open, or robotic assisted stone removal. (Index patient 1-6) (*Moderate Recommendation; Evidence Level Grade C*)
Clinicians performing URS for proximal ureteral stones should have a flexible ureteroscope available. (Index Patients 1, 4) (*Clinical Principle*)
Clinicians should not utilize electrohydraulic lithotripsy (EHL) as the first-line modality for intra-ureteral lithotripsy. (Index patients 1-6,13,15) (*Expert Opinion*)
In patients with obstructing stones and suspected infection, clinicians must urgently drain the collecting system with a stent or nephrostomy tube and delay stone treatment. (*Strong Recommendation; Evidence Level Grade C*)

Treatment of Adult Patients with Renal Stones

In symptomatic patients with a total non-lower pole renal stone burden ≤20 mm, clinicians may offer SWL or URS. (Index Patient 7) (*Strong Recommendation; Evidence Level Grade B*)
In symptomatic patients with a total renal stone burden >20 mm, clinicians should offer PCNL as first-line therapy. (Index Patient 8) (*Strong Recommendation; Evidence Level Grade C*)
In patients with total renal stone burden >20 mm, clinicians should not offer SWL as first-line therapy. (Index Patient 8) (*Moderate Recommendation; Evidence Level Grade C*)
Clinicians may perform nephrectomy when the involved kidney has negligible function in patients requiring treatment. (Index Patients 1-14) (*Conditional Recommendation; Evidence Level Grade C*)
For patients with symptomatic (flank pain), non-obstructing, caliceal stones without another obvious etiology for pain, clinicians may offer stone treatment. (Index Patient 12) (*Moderate Recommendation; Evidence Level Grade C*)
For patients with asymptomatic, non-obstructing caliceal stones, clinicians may offer active surveillance. (*Conditional Recommendation; Evidence Level Grade C*)
Clinicians should offer SWL or URS to patients with symptomatic ≤10 mm lower pole renal stones. (Index Patient 9) (*Strong Recommendation; Evidence Level Grade B*)
Clinicians should not offer SWL as first-line therapy to patients with >10 mm lower pole stones. (Index Patient 10) (*Strong Recommendation; Evidence Level Grade B*)
Clinicians should inform patients with lower pole stones >10 mm in size that PCNL has a higher stone-free rate but greater morbidity. (Index Patient 10). (*Strong Recommendation; Evidence Level Grade B*)
In patients undergoing uncomplicated PCNL who are presumed stone-free, placement of a nephrostomy tube is optional. (*Conditional Recommendation; Evidence Level Grade C*)
Flexible nephroscopy should be a routine part of standard PCNL. (*Strong Recommendation; Evidence Level Grade B*)
Clinicians must use normal saline irrigation for PCNL and URS. (*Strong Recommendation; Evidence Level Grade B*)
In patients not considered candidates for PCNL, clinicians may offer staged URS. (*Moderate Recommendation; Evidence Level Grade C*)
Clinicians may prescribe α-blockers to facilitate passage of stone fragments following SWL. (*Moderate Recommendation; Evidence Level Grade B*)
SWL should not be used in the patient with anatomic or functional obstruction of the collecting system or ureter distal to the stone. (*Strong Recommendation; Evidence Level Grade C*)
In patients with symptomatic caliceal diverticular stones, endoscopic therapy (URS, PCNL, laparoscopic, robotic) should be preferentially utilized. (*Strong Recommendation; Evidence Level Grade C*)
Staghorn stones should be removed if attendant comorbidities do not preclude treatment. (*Clinical Principle*)

Treatment for Pediatric Patients with Ureteral or Renal Stones

In pediatric patients with uncomplicated ureteral stones ≤10 mm, clinicians should offer observation with or without MET using α-blockers. (Index Patient 13) (*Moderate Recommendation; Evidence Level Grade B*)

Clinicians should offer URS or SWL for pediatric patients with ureteral stones who are unlikely to pass the stones or who failed observation and/or MET, based on patient-specific anatomy and body habitus. (Index Patient 13) (*Strong Recommendation; Evidence Level Grade B*)

Clinicians should obtain a low-dose CT scan on pediatric patients prior to performing PCNL. (Index Patient 13) (*Strong Recommendation; Evidence Level Grade C*)

In pediatric patients with ureteral stones, clinicians should not routinely place a stent prior to URS. (Index Patient 13) (*Expert Opinion*)

In pediatric patients with a total renal stone burden ≤20mm, clinicians may offer SWL or URS as first-line therapy. (Index Patient 14) (*Moderate Recommendation; Evidence Level Grade C*)

In pediatric patients with a total renal stone burden >20mm, both PCNL and SWL are acceptable treatment options. If SWL is utilized, clinicians should place an internalized ureteral stent or nephrostomy tube. (Index Patient 14) (*Expert Opinion*)

In pediatric patients, except in cases of coexisting anatomic abnormalities, clinicians should not routinely perform open/laparoscopic/robotic surgery for upper tract stones. (Index Patients 13, 14) (*Expert Opinion*)

In pediatric patients with asymptomatic and non-obstructing renal stones, clinicians may utilize active surveillance with periodic ultrasonography. (Index Patient 14) (*Expert Opinion*)

Treatment for Pregnant Patients with Ureteral or Renal Stones

In pregnant patients, clinicians should coordinate pharmacological and surgical intervention with the obstetrician. (Index Patient 15) (*Clinical Principle*)

In pregnant patients with ureteral stones and well controlled symptoms, clinicians should offer observation as first-line therapy. (Index Patient 15) (*Strong recommendation; Evidence Level Grade B*)

In pregnant patients with ureteral stones, clinicians may offer URS to patients who fail observation. Ureteral stent and nephrostomy tube are alternative options with frequent stent or tube changes usually being necessary. (Index Patient 15) (*Strong Recommendation; Evidence Level Grade C*)

Treatment for All Patients with Ureteral or Renal Stones

When residual fragments are present, clinicians should offer patients endoscopic procedures to render the patients stone free, especially if infection stones are suspected. (Index Patient 11) (*Moderate Recommendation; Evidence Level Grade C*)

Stone material should be sent for analysis. (*Clinical Principle*)

Open/laparoscopic/robotic surgery should not be offered as first-line therapy to most patients with stones. Exceptions include rare cases of anatomic abnormalities, with large or complex stones, or those requiring concomitant reconstruction. (Index Patients 1-15) (*Strong Recommendation; Evidence Level Grade C*)

A safety guide wire should be used for most endoscopic procedures. (Index Patients 1-15) (*Expert Opinion*)

Antimicrobial prophylaxis should be administered prior to stone intervention and is based primarily on prior urine culture results, the local antibiogram, and in consultation with the current Best Practice Policy Statement on Antibiotic Prophylaxis. (*Clinical Principle*)

Clinicians should abort stone removal procedures, establish appropriate drainage, continue antibiotic therapy, and obtain a urine culture if purulent urine is encountered during endoscopic intervention. (Index Patients 1-15) (*Strong Recommendation; Evidence Level Grade C*)

If initial SWL fails, clinicians should offer endoscopic therapy as the next treatment option. (Index Patient 1-14) (*Moderate Recommendation; Evidence Level Grade C*)

Clinicians should use URS as first-line therapy in most patients who require stone intervention in the setting of uncorrected bleeding diatheses or who require continuous anticoagulation/antiplatelet therapy. (Index Patients 1-15) (*Strong Recommendation; Evidence Level Grade C*)

Definitions

Body of Evidence Strength

Grade A: Well-conducted and highly-generalizable randomized controlled trials (RCTs) or exceptionally strong observational studies with consistent findings

Grade B: RCTs with some weaknesses of procedure or generalizability or moderately strong observational studies with consistent findings

Grade C: RCTs with serious deficiencies of procedure, generalizability, or extremely small sample sizes or observational studies that are inconsistent, have small sample sizes, or have other problems that potentially confound interpretation of data

Note: By definition, Grade A evidence is evidence about which the Panel has a high level of certainty, Grade B evidence is evidence about which the Panel has a moderate level of certainty, and Grade C evidence is evidence about which the Panel has a low level of certainty.

American Urological Association (AUA) Nomenclature Linking Statement Type to Level of Certainty, Magnitude of Benefit or Risk/Burden, and Body of Evidence Strength

	Evidence Strength A (High Certainty)	**Evidence Strength B (Moderate Certainty)**	**Evidence Strength C (Low Certainty)**
Strong Recommendation (Net benefit or harm substantial)	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) is substantial Applies to most patients in most circumstances and future research is unlikely to change confidence	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) is substantial Applies to most patients in most circumstances but better evidence could change confidence	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) appears substantial Applies to most patients in most circumstances but better evidence is likely to change confidence (rarely used to support a Strong Recommendation)
Moderate Recommendation (Net benefit or harm moderate)	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) is moderate Applies to most patients in most circumstances and future research is unlikely to change confidence	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) is moderate Applies to most patients in most circumstances but better evidence could change confidence	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) appears moderate Applies to most patients in most circumstances but better evidence could change confidence
Conditional Recommendation (No apparent net benefit or harm)	Benefits = Risks/Burdens Best action depends on individual patient circumstances Future research unlikely to change confidence	Benefits = Risks/Burdens Best action depends on individual patient circumstances Better evidence could change confidence	Balance between Benefits & Risks/Burdens unclear Alternative strategies may be equally reasonable Better evidence likely to change confidence
Clinical Principle	A statement about a component of clinical care that is widely agreed upon by urologists or other clinicians for which there may or may not be evidence in the medical literature		
Expert Opinion	A statement, achieved by consensus of the Panel, that is based on members' clinical training, experience, knowledge, and judgment for which there is no evidence		

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Kidney and/or ureteral stones

Guideline Category

Evaluation

Management

Treatment

Clinical Specialty

Internal Medicine

Nephrology

Obstetrics and Gynecology

Pediatrics

Radiology

Surgery

Urology

Intended Users

Physicians

Guideline Objective(s)

- To provide a clinical framework for the surgical management of patients with kidney and/or ureteral stones
- To revise previously published American Urological Association (AUA) Guidelines titled Staghorn Calculi (2005) and Ureteral Calculi (2007) and to incorporate the management of patients with non-staghorn renal stones

Target Population

Adult (≥18 years of age), pediatric (<18 years of age), and pregnant patients with kidney and/or ureteral stones

Interventions and Practices Considered

1. Imaging/pre-operative testing

- Non-contrast computed tomography (CT) scan
- Functional imaging study (diethylenetriamine-pentacetic acid [DTPA] or (mercaptoacetyltriglycine [MAGâ€3])
- Urinalysis
- Complete blood count and platelet count
- Serum electrolytes
- Creatinine
- Contrast imaging

2. Treatment/management
    - Observation
    - Medical expulsive therapy (MET)
    - Shock wave lithotripsy (SWL)
    - Ureteroscopy (URS)
    - Reimaging
    - Placement of a ureteral stent or nephrostomy tube
    - Use of α-blockers and antimuscarinic therapy to reduce stent discomfort
    - Percutaneous nephrolithotomy (PCNL)
    - Use of laparoscopic, open, or robotic assisted stone removal (not recommended as first-line therapy)
    - Electrohydraulic lithotripsy (EHL) (not recommended as the first-line modality for intra-ureteral lithotripsy)
    - Use of a safety guide wire with endoscopic procedures
    - Nephrectomy
    - Active surveillance
    - Removal of staghorn stones
    - Analysis of stone material
    - Antimicrobial prophylaxis
    - Obtaining a urine culture if purulent urine is encountered
    - Special considerations for pediatric and pregnant patients and for renal versus ureteral stones

Major Outcomes Considered

- Stone-free rates (as determined by kidneys, ureters, and bladder radiography [KUB], ultrasound [US], intravenous pyelogram [IVP], nephrotomogram, computed tomography [CT], endoscopy)
- Residual fragments (capture sizes)
- Secondary procedures needed (stone-removing vs. ancillary)
- Quality of life
- Pain
- Analgesic requirements
- Length of hospitalization
- Comparative recurrence rates
- Renal function
- Radiation exposure
- Complications (death, sepsis, urinary tract infection [UTI], loss of kidney, etc.)

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Methodology

Process for Initial Literature Selection

Consistent with the published American Urological Association (AUA) Guideline methodology framework, the process started by conducting a comprehensive systematic review. The AUA commissioned an independent group to conduct a systematic review and meta-analysis of the published literature on various options for the surgical management of stones. The protocol of the systematic review was developed *a priori* by the methodology team in conjunction with the expert panel. A systematic review was conducted to identify published articles relevant to the surgical management of renal or ureteral stones.

Literature searches were performed on English-language publications using the Medline In-Process & Other Non-Indexed Citations, MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, and Scopus from 1/1/1985 to 5/31/2015.

Preclinical studies (e.g., animal models), commentary, and editorials were excluded. Studies on patients with lower tract stones were excluded (including bladder stones and diversions). Bibliographies of review articles were checked to ensure inclusion of all possibly relevant studies. Multiple reports on the same patient group were carefully examined to ensure inclusion of only non-redundant information.

Number of Source Documents

The systematic review yielded a total of 1,911 studies. The Panel and methodology group continued to monitor the literature for relevant randomized trials thereafter and added several newer trials published through 2015.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Body of Evidence Strength

Grade A: Well-conducted and highly-generalizable randomized controlled trials (RCTs) or exceptionally strong observational studies with consistent findings

Grade B: RCTs with some weaknesses of procedure or generalizability or moderately strong observational studies with consistent findings

Grade C: RCTs with serious deficiencies of procedure, generalizability, or extremely small sample sizes or observational studies that are inconsistent, have small sample sizes, or have other problems that potentially confound interpretation of data

Note: By definition, Grade A evidence is evidence about which the Panel has a high level of certainty, Grade B evidence is evidence about which the Panel has a moderate level of certainty, and Grade C evidence is evidence about which the Panel has a low level of certainty.

Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Data on study type (e.g., randomized controlled trial [RCT], controlled clinical trial [CCT], observational study), perioperative testing, treatment parameters (e.g., type of treatment), patient characteristics (e.g., age, stone size and location), outcomes (e.g., stone-free rate, residual fragments, quality of life [QoL]) and complications were extracted.

Almost all the studies that reported on preoperative testing (99 computed tomography [CT] scan, 10 renal scan, 128 renal ultrasound [US], 188 kidney-ureter-bladder (KUB), 156 intravenous pyelogram [IVP], 68 complete blood count [CBC], 29 stone analysis and 112 urine culture) did not report the purpose of performing these tests. There were no reliable data on the utility or incremental value of testing. The procedures of interest were percutaneous nephrolithotomy (PCNL), ureteroscopy (URS), laparoscopy, shock-wave lithotripsy (SWL), open surgery, robotic surgery, ureteral stent, or nephrostomy. Comparison of any of these active treatments against each other or against medical management was done when possible. Medical expulsive therapy (MET) was evaluated in terms of efficacy against placebo. Outcomes included stone-free rate (as determined by KUB, US, IVP, nephrotomogram, computed tomography [CT], endoscopy); residual fragments (by size); secondary procedures needed (stone-removing versus ancillary); QoL; pain; analgesic requirements; length of hospitalization; comparative recurrence rates; renal function; and procedure complications (e.g., death, sepsis/systemic inflammatory response syndrome [sirs], transfusion, loss of kidney, readmission rates, overall rates). When multiple studies evaluated the same outcome and had similar population, intervention, and comparison, meta-analysis was conducted using the random effects model, when appropriate. Stone-free rate was stratified based on stone size and location.

The methodology team independently rated the methodological quality of the studies and provided an overall judgment of the whole body of evidence based on confidence in the available estimates of effect.

The methodology team summarized the data with explicit description of study characteristics, methodological quality, main findings, and quality of the evidence (confidence in the estimates). The methodology team attended panel meetings and facilitated incorporation of the evidence into the Guideline.

Quality of Individual Studies and Determination of Evidence Strength

The quality of individual studies that were either RCTs or CCTs was assessed using the Cochrane Risk of Bias tool. The quality of CCTs and comparative observational studies was rated using the Newcastle-Ottawa Quality (NOQ) Assessment Scale. Because there is no widely-agreed upon quality assessment tool for single cohort observational studies, the quality of these studies was not assessed.

The categorization of evidence strength is conceptually distinct from the quality of individual studies (the latter is also called the risk of bias). Evidence strength refers to the body of evidence available for a particular question and includes not only individual study quality but consideration of study design; consistency of findings across studies; adequacy of sample sizes; and generalizability of samples, settings, and treatments for the purposes of the guideline (see the "Rating Scheme for the Strength of Evidence" field).

Methods Used to Formulate the Recommendations

Expert Consensus

Expert Consensus (Delphi)

Description of Methods Used to Formulate the Recommendations

This document was written by the Surgical Management of Stones Guideline Panel of the American Urological Association Education and Research, Inc. (AUA), which was created in 2014. The Practice Guidelines Committee (PGC) of the AUA selected the committee chair. Panel members were selected by the chair. Membership of the panel included specialists in urology with specific expertise on this disorder. The mission of the panel was to develop recommendations that are analysis-based or consensus-based, depending on panel processes and available data, for optimal clinical practices in the treatment of stones.

AUA Nomenclature: Linking Statement Type to Evidence Strength

The AUA nomenclature system links statement type to body of evidence strength, level of certainty, magnitude of benefit or risks/burdens, and the Panel's judgment regarding the balance between benefits and risks/burdens (see the "Rating Scheme for the Strength of the Recommendations" field).

For some clinical issues, particularly diagnosis, there was little or no evidence from which to construct evidence-based statements. Where gaps in the evidence existed, the Panel provides guidance in the form of Clinical Principles or Expert Opinions with consensus achieved using a modified Delphi technique if differences of opinion emerged.

Rating Scheme for the Strength of the Recommendations

American Urological Association (AUA) Nomenclature Linking Statement Type to Level of Certainty, Magnitude of Benefit or Risk/Burden, and Body of Evidence Strength

	Evidence Strength A (High Certainty)	**Evidence Strength B (Moderate Certainty)**	**Evidence Strength C (Low Certainty)**
Strong Recommendation (Net benefit or harm substantial)	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) is substantial Applies to most patients in most circumstances and future research is unlikely to change confidence	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) is substantial Applies to most patients in most circumstances but better evidence could change confidence	Benefits > Risks/Burdens (or vice versa) Net benefit (or net harm) appears substantial Applies to most patients in most circumstances but better evidence is likely to change confidence (rarely used to support a Strong Recommendation)
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Conditional Recommendation (No apparent net benefit or harm)	Benefits = Risks/Burdens Best action depends on individual patient circumstances	Benefits = Risks/Burdens Best action depends on individual patient circumstances	Balance between Benefits & Risks/Burdens unclear Alternative strategies may be equally reasonable Better evidence likely to change

	Evidence Strength A (High Certainty)	Evidence Strength B (Moderate Certainty)	Evidence Strength C (Low Certainty)
	Future research unlikely to change confidence	Better evidence could change confidence	confidence
Clinical Principle	A statement about a component of clinical care that is widely agreed upon by urologists or other clinicians for which there may or may not be evidence in the medical literature		
Expert Opinion	A statement, achieved by consensus of the Panel, that is based on members' clinical training, experience, knowledge, and judgment for which there is no evidence		

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Peer Review

Description of Method of Guideline Validation

The American Urological Association Education and Research, Inc. (AUA) conducted a thorough peer review process. The draft guidelines document was distributed to 109 peer reviewers, 54 of whom provided comments. The Panel reviewed and discussed all submitted comments and revised the draft as needed. Once finalized, the Guideline was submitted for approval to the Practice Guidelines Committee (PGC) and Science and Quality Council (S&Q). Then it was submitted to the AUA Board of Directors and the Endourological Society Board of Directors for final approval. It was approved by the AUA Board of Directors in April 2016.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations" field).

For some clinical issues, particularly diagnosis, there was little or no evidence from which to construct evidence-based statements. Where gaps in the evidence existed, the Panel provides guidance in the form of *Clinical Principles* or *Expert Opinions* with consensus.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Selection of appropriate particular treatment modalities for kidney and/or ureteral stone elimination

The magnitude of benefit or risk/burdens, and the Panel's judgment regarding the balance between benefits and risks/burdens are taken into account for each guideline statement. Refer to the original guideline document for a discussion of evidence of benefits for specific statements.

Potential Harms

- Procedure complications include death, sepsis/systemic inflammatory response syndrome (sirs), loss of kidney, urinary tract infections (UTIs), ureteral stricture, ureteral injury, and unplanned emergency room visits.
- In an older randomized prospective trial comparing percutaneous nephrolithotomy (PCNL) to shock-wave lithotripsy (SWL) for the treatment of staghorn calculi, the author found a three-fold higher stone-free rate with PCNL combination therapy (PCNL/SWL) than with SWL monotherapy. In addition, the rate of sepsis is significantly higher with SWL.
- Despite computed tomography's (CT's) diagnostic superiority over other imaging tests, it is incumbent on urologists to be cognizant of the potential risks/harms of the investigations they select for their patients to accurately diagnose and plan appropriate therapies. Concerns regarding the long-term cancer risks associated with ionizing radiation have led to calls for the use of ultrasound (US) in the initial diagnosis of acute flank pain.
- The present Panel's analysis revealed that the risk of ureteral perforation is significantly higher during ureteroscopy (URS) versus SWL (median 3.2% versus 0%, respectively). Likewise, the 2007 European Association of Urology (EAU)/American Urological Association (AUA) Guideline for the Management of Ureteral Calculi found a higher complication rate for URS compared to SWL for stones in all locations in the ureter: 11% versus 4%, respectively, for proximal ureteral stones; 14% versus 4%, respectively, for middle ureteral stones; and 7% versus 1%, respectively, for distal ureteral stones.
- The major disadvantage of electrohydraulic lithotripsy (EHL) is its propensity to damage the ureteral mucosa, resulting in ureteral perforation. It is speculated that the expanding cavitation bubble generated by the spark may produce injury to the mucosa even when the probe is not in direct contact with the urothelium, with reported rates of ureteral injury of 8.5% to 17.6%.
- A recent systematic review and meta-analysis of PCNL versus URS reported higher complication rates for PCNL (odds ratio 1.61; 95% confidence interval 1.11-2.35). The CROES PCNL Global Study reported a 15% overall complication rate with the majority of complications categorized as Clavien Grade I. Bleeding necessitating blood transfusion was the most common complication at 7%.
- Studies have demonstrated morbidity associated with indwelling nephrostomy tubes following PCNL, specifically increased postoperative pain with greater narcotic requirements and increased length of hospitalization.
- It is well recognized that ureteral stents are the source of significant morbidity.

The magnitude of benefit or risk/burdens, and the Panel's judgment regarding the balance between benefits and risks/burdens are taken into account for each guideline statement. Refer to the original guideline document for additional discussion of evidence of harms for specific statements.

Contraindications

Contraindications

- While percutaneous nephrolithotomy (PCNL) is the optimal treatment for most patients with complex, high-volume, and branched renal stones, some anatomic abnormalities and/or patient factors may provide relative contraindications to PCNL, including use of anti-coagulation or anti-platelet therapy that cannot be discontinued or the presence of contractures, flexion deformities, or other anatomic derangements that may preclude positioning for PCNL.
- Non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., ketorolac) are contraindicated in pregnancy.

Qualifying Statements

Qualifying Statements

- While these guidelines do not necessarily establish the standard of care, the American Urological Association Education and Research, Inc. (AUA) seeks to recommend and to encourage compliance by practitioners with current best practices related to the condition being treated. As medical knowledge expands and technology advances, the guidelines will change. Today these evidence-based guidelines statements represent not absolute mandates but provisional proposals for treatment under the specific conditions described in each document. For all these reasons, the guidelines do not pre-empt physician judgment in individual cases.
- Treating physicians must take into account variations in resources, and patient tolerances, needs, and preferences. Conformance with any clinical guideline does not guarantee a successful outcome. The guideline text may include information or recommendations about certain drug uses ('off label') that are not approved by the U.S. Food and Drug Administration (FDA), or about medications or substances not subject to the FDA approval process. AUA urges strict compliance with all government regulations and protocols for prescription and use of these substances. The physician is encouraged to carefully follow all available prescribing information about indications, contraindications, precautions and warnings. These guidelines and best practice statements are not in-tended to provide legal advice about use and misuse of these substances.
- Although guidelines are intended to encourage best practices and potentially encompass available technologies with sufficient data as of close of the literature review, they are necessarily time-limited. Guidelines cannot include evaluation of all data on emerging technologies or management, including those that are FDA-approved, which may immediately come to represent accepted clinical practices. For this reason, the AUA does not regard technologies or management which are too new to be addressed by this guideline as necessarily experimental or investigational.

Limitations of the Literature

Evidence to guide perioperative diagnostic evaluation was sparse and of low quality, affecting recommendations on laboratory testing and imaging. Data on stone-free rate (lithotripsy, ureteroscopy [URS] and percutaneous nephrolithotomy [PCNL]) when stratified by location and stone size were also limited in clinical trials; therefore, rates were also derived from large registries that provided precise, although likely biased, estimates. Comparative effectiveness of medical expulsive therapy (MET) was derived from a large number of trials that overall has a moderate risk of bias. Only a very small number of studies were available to provide comparative effectiveness inferences in children.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Mobile Device Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Assimos D, Krambeck A, Miller NL, Monga M, Murad MH, Nelson CP, Pace KT, Pais VM Jr, Pearle MS, Preminger GM, Razvi H, Shah O, Matlaga BR. Surgical management of stones: American Urological Association/Endourological Society guideline. Linthicum (MD): American Urological Association Education and Research, Inc.; 2016 Apr. 50 p. [235 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

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Guideline Developer(s)

American Urological Association Education and Research, Inc. - Medical Specialty Society

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Guideline Committee

Surgical Management of Stones Guideline Panel

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

Conflict of Interest (COI) Disclosures

All panel members completed COI disclosures. Those marked with (C) indicate that compensation was received. Disclosures listed include both topic- and non–topic-related relationships.

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Scientific Study or Trial: Dean Assimos, National Institute of Health (NIH) (C);

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Guideline Status

This is the current release of the guideline.

This guideline updates previous versions: EAU/AUA Nephrolithiasis Guideline Panel. Guideline for the management of ureteral calculi. Baltimore (MD): American Urological Association Education and Research, Inc., European Association of Urology; 2007. 61 p. [92 references]

American Urological Association Education and Research, Inc. Report on the management of staghorn calculi. Linthicum (MD): American Urological Association Education and Research, Inc.; 2005. Various p. [81 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the American Urological Association Education and Research, Inc. (AUA) Web site .

Availability of Companion Documents

The AUA Guidelines-At-A-Glance mobile app is available for download from the American Urological Association Education and Research, Inc. (AUA) Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI on September 1, 1998. It was verified by the guideline developer on December 1, 1998. This summary was updated by ECRI Institute on March 21, 2008. The updated information was verified by the guideline developer on April 1, 2008. The currency of the guideline was reaffirmed by the developer in 2010 and this summary was updated by ECRI Institute on October 16, 2012. This summary was updated by ECRI Institute on September 29, 2016. The updated information was not verified by the guideline developer.

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